

Koenig, Michael

From: Koenig, Michael
Sent: Wednesday, August 25, 2004 3:19 PM
To: 'Frederick Stearns'
Cc: Holman, Matthew Ray; Olin, Keith
Subject: USP monograph for piroctone olamine

Dear Mr. Stearns:

We have received data to support the safety and effectiveness of piroctone olamine as an anti-dandruff active ingredient. Thank you for the submission.

Your submission included a "Proposed OTC Monograph for Piroctone Olamine (Octopirox®)" on pages 52 – 54 (vol. 1 of 6). You may have misinterpreted the requirement, stated in the Notice of Eligibility (69 FR 7652 at 7653), which stipulated that "an official or proposed USP–NF monograph for piroctone olamine must be included as part of the safety and effectiveness data for this ingredient." This monograph must be established with the USP. Because no official USP monograph exists for piroctone olamine, we will need a monograph *proposed by the USP* for inclusion in a later revision of the USP–NF listing.

Information on how to go about doing this can be obtained from the USP website: <http://www.usp.org/standards/revisionguideline/index.html>. You may also wish to call Dr. Lawrence Evans at the USP. Dr. Evans has been involved in preparing the monographs for at least three other anti-dandruff active ingredients. Dr. Evans' phone number is listed as (301) 816-8389.

Sincerely,
Mike Koenig

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